under § 1240.63(a)(2)(ii) will be 480 hours (120 respondents x 4 hours per response = 480 hours).

In the **Federal Register** of February 19, 2004 (69 FR 7752), FDA published a 60-day notice requesting public comment on the information collection provisions. We received nearly 700 comments on the interim final rule and the notice that invited public comment on the proposed collection of information. Over 140 of these comments were submitted after February 19, 2004 (the date on which we published the notice concerning the collection of information), but the majority of these later comments apparently interpreted that notice as another opportunity to comment on the interim final rule's merits rather than comment on the collection of information itself. This notice simply announces that we are seeking renewal of OMB's paperwork approval for the interim final rule and addresses those comments regarding the collection of information. It is not an issuance of a final rule and we are not seeking additional comments on the interim final rule.

Of the few comments that may pertain to the collection of information, none agreed with the collection of information or the estimates themselves. Here we address the comments on the collection of information, not the comments on the substance of the rule itself.

Some comments claimed that we take 2 1/2 to 4 months to process a permit request. Of these comments, some also claimed that the permit process was too burdensome because State agencies had to be involved. One comment claimed that the permit process requires a person to describe the benefits that would result if we granted the permit and indicated that it is sometimes difficult to show a benefit.

We disagree with the comments for several reasons. First, we disagree with the claim that our permit process takes several months to complete. While permit requests vary in their complexity, and complex and incomplete requests may take more time to process, our records indicate that we respond to permit requests, on average, within 27 days (including weekends and holidays).

Second, although a person seeking a permit must also comply with all State and local requirements related to the handling and transport of animals subject to the interim final rule, nothing in the interim final rule's permit provision requires a person to contact State agencies as part of FDA's permit process. We may consult State agencies about a particular permit request, but this consultation does not create an information collection burden on the person requesting the permit. Furthermore, the interim final rule does not require a person seeking a permit to describe the benefit that would result if we granted their request. The interim final rule does require a person to explain why an exemption will not result in the spread of monkeypox in the United States, and this explanation can be derived from the facts accompanying the permit request. For example, the description of the animals involved (species, absence of contact with infected animals, the animals' origin) may help explain why the animals involved do not present a risk of having the monkeypox virus. The description of the precautions taken may help explain why there is no risk of spreading the monkeypox virus. In other words, the interim final rule does not require a person to show that a ''benefit'' would result if we granted the permit, but it does seek information to help us assess the risk associated with the request.

Other comments appeared to address the estimated number of respondents or our data. One comment stated that it believed the estimated number of respondents (i.e., persons who would request a permit) is too low, although it offered no different estimates itself. The comment further stated that there are people who are ignoring the rule or are unaware of the rule, but offered no estimates. Another comment declared ''there are major flaws with the data collection in this docket,'' but did not discuss the permit process or any specific estimate.

As we explained in the February 19, 2004, notice, we based our estimates on our experience with the permit process, including the experience of those submitting permit requests. We have no reasonable basis for adjusting our estimates to reflect the possibility that persons are either intentionally or unintentionally failing to seek permits, and the comments offered none. Consequently, in the absence of any new data or conflicting estimates, we decline to revise our estimates.

Dated: July 2, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–15658 Filed 7–8–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0103]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Special Protocol Assessment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by August 9, 2004.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry on Special Protocol Assessment—(OMB Control Number 0910–0470)—Extension

In the **Federal Register** of March 22, 2004 (69 FR 13304), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

The ''Guidance for Industry on Special Protocol Assessment'' (69 FR 13304) describes agency procedures to evaluate issues related to the adequacy (e.g., design, conduct, analysis) of certain proposed studies. The guidance describes procedures for sponsors to request special protocol assessment and for the agency to act on such requests. The guidance provides information on how the agency will interpret and apply

provisions of the Food and Drug Administration Modernization Act of 1987 and the specific Prescription Drug User Fee Act of 1992 (PDUFA) goals for special protocol assessment associated with the development and review of PDUFA products.

The guidance describes two collections of information: (1) The submission of a notice of intent to request special protocol assessment of a carcinogenicity protocol, and (2) the submission of a request for special protocol assessment.

A. Notification for a Carcinogenicity Protocol

As described in the guidance, a sponsor interested in agency assessment of a carcinogenicity protocol should notify the appropriate division in FDA's Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER) of an intent to request special protocol assessment at least 30 days prior to submitting the request. With such notification, the sponsor should submit relevant background information so that the agency may review reference material related to carcinogenicity protocol design prior to receiving the carcinogenicity protocol.

B. Request for Special Protocol Assessment

In the guidance, CDER and CBER ask that a request for special protocol assessment be submitted as an amendment to the investigational new drug application (IND) for the underlying product and that it be submitted to the agency in triplicate with Form FDA 1571 attached. The agency also suggests that the sponsor submit the cover letter to a request for special protocol assessment via facsimile to the appropriate division in CDER or CBER. Agency regulations (§ 312.23(d)) state that information provided to the agency as part of an IND is to be submitted in triplicate and with the appropriate cover form, Form FDA 1571. An IND is submitted to FDA under existing regulations in part 312 (21 CFR part 312), which specifies the information that manufacturers must submit so that FDA may properly evaluate the safety and effectiveness of investigational drugs and biological products. The information collection requirements resulting from the preparation and submission of an IND under part 312 have been estimated by FDA and the reporting and recordkeeping burden has been approved by OMB until January 31, 2006, under OMB control number 0910–0014.

FDA suggests that the cover letter to the request for special protocol assessment be submitted via facsimile to the appropriate division in CDER or CBER to enable agency staff to prepare for the arrival of the protocol for assessment. The agency recommends that a request for special protocol assessment be submitted as an amendment to an IND for two reasons: (1) To ensure that each request is kept in the administrative file with the entire IND, and (2) to ensure that pertinent information about the request is entered into the appropriate tracking databases. Use of the information in the agency's tracking databases enables the appropriate agency official to monitor progress on the evaluation of the protocol and to ensure that appropriate steps will be taken in a timely manner.

CDER and CBER have determined and the guidance recommends that the following information should be submitted to the appropriate Center with each request for special protocol assessment so that the Center may quickly and efficiently respond to the request:

- Questions to the agency concerning specific issues regarding the protocol; and
- All data, assumptions, and information needed to permit an adequate evaluation of the protocol, including: (1) The role of the study in the overall development of the drug; (2) information supporting the proposed trial, including power calculations, the choice of study endpoints, and other critical design features; (3) regulatory outcomes that could be supported by the results of the study; (4) final labeling that could be supported by the results of the study; and (5) for a stability protocol, product characterization and relevant manufacturing data.

Description of Respondents: A sponsor, applicant, or manufacturer of a drug or biologic product regulated by the agency under the Federal Food, Drug, and Cosmetic Act (the act) or section 351 of the Public Health Service Act (42 U.S.C. 262) who requests special protocol assessment.

Burden Estimate: Table 1 of this document provides an estimate of the annual reporting burden for requests for special protocol assessment. The procedures for requesting special protocol assessment that are set forth in the guidance document have not been previously described by the agency, although the PDUFA goals and the requirements of section 505(b)(4)(B) of the act (21 U.S.C. 355(b)(4)(B)) have been in effect since October and November 1998, respectively.

Notification for a Carcinogenicity Protocol. Based on data collected from the review divisions and offices within CDER and CBER, including the number of notifications for carcinogenicity protocols and the number of carcinogenicity protocols submitted in fiscal year (FY) 2003, CDER estimates that it will receive approximately 40 notifications of an intent to request special protocol assessment of a carcinogenicity protocol per year from approximately 20 sponsors. CBER anticipates one notification. The hours per response, which is the estimated number of hours that a sponsor would spend preparing the notification and background information to be submitted in accordance with the guidance, is estimated to be approximately 8 hours.

Requests for Special Protocol Assessment. Based on data collected from the review divisions and offices within CDER and CBER, including the number of requests for special protocol assessment submitted in FY 2003, CDER estimates that it will receive approximately 273 requests for special protocol assessment per year from approximately 102 sponsors. CBER estimates that it will receive approximately 20 requests from approximately 12 sponsors. The hours per response is the estimated number of hours that a respondent would spend preparing the information to be submitted with a request for special protocol assessment, including the time it takes to gather and copy questions to be posed to the agency regarding the protocol and data, assumptions, and information needed to permit an adequate evaluation of the protocol. Based on the agency's experience with these submissions, FDA estimates approximately 15 hours on average would be needed per response. Overall, FDA estimates that respondents will spend 4,523 hours per year to participate in the programs described in the guidance document.

FDA estimates the burden of this collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Notification for carcinogenicity protocols	21	1.78	41	8	328
Requests for special protocol assessment	114	2.57	293	15	4,395
Total					4,723

[1] There are no capital costs or operating and maintenance costs associated with this collection.

Dated: July 2, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–15659 Filed 7–8–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0161]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Request for Information From United States Processors That Export to the European Community

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by August 9, 2004.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Request for Information From U.S. Processors That Export to the European Community—(OMB Control Number 0910–0320)—Extension

The European Community (EC) is a group of 15 European countries (with 10 additional countries joining on May 1, 2004), that have agreed to harmonize their commodity requirements to facilitate commerce among member States. EC legislation for intraEC trade has been extended to trade with nonEC countries, including the United States. For certain food products, including those listed in this document, EC legislation requires assurances from the responsible authority of the country of origin that the processor of the food is in compliance with applicable regulatory requirements.

With the assistance of trade associations and State authorities, FDA requests information from processors that export certain animal-derived products (e.g., shell eggs, dairy products, game meat, game meat products, animal casings, and gelatin) to EC. FDA uses the information to maintain lists of processors that have demonstrated current compliance with U.S. requirements and provides the lists to EC quarterly. Inclusion on the list is voluntary. EC member countries refer to the lists at ports of entry to verify that products offered for importation to EC from the United States are from processors that meet U.S. regulatory requirements. Products processed by firms not on the list are subject to detention and possible refusal at the port. FDA requests the following information from each processor:

(1) Business name and address;

(2) Name and telephone number of person designated as business contact;

(3) Lists of products presently being shipped to EC and those intended to be shipped in the next 6 months;

(4) Name and address of manufacturing plants for each product;

(5) Names and affiliations of any Federal, State, or local governmental agencies that inspect the plant, government-assigned plant identifier such as plant number, and last date of inspection; and

(6) Assurance that the firm or individual representing the firm and submitting a certificate for signature to FDA is aware of and knows that they are subject to the provisions of 18 U.S.C. 1001. This law provides that it is a criminal offense to knowingly and willfully make a false statement or alter or counterfeit documents in a matter within the jurisdiction of a U.S. agency.

In the **Federal Register** of April 16, 2004 (69 FR 20630), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden of this collection of information as follows: